


## BOZICEVIC, FIELD &amp; FRANCIS LLP

INTELLECTUAL PROPERTY LAW

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Date: October 11, 2007

To: Certificate of Correction Branch	Fax: 703-308-6672	<input checked="" type="checkbox"/> Use this fax number only
Company: USPTO	Phone: 703-305-8309	<input type="checkbox"/> Notify recipient before sending
From: Bret E. Field c/o Wilhelm Palmen	Phone: (650) 327-3400	Return Fax: (650) 327-3231
Original: <input type="checkbox"/> To follow via mail <input type="checkbox"/> To follow via courier <input type="checkbox"/> To follow via email <input checked="" type="checkbox"/> Original will not follow		
Fax Contains: 8 pages (including this sheet). If incomplete, please call Emily R. Almonte at (650) 833-7736.		
<b>Message:</b>		
Re: U.S Patent No. 6,761,900 Issued July 13, 2004 <u>Status Inquiry for Certificate of Correction filed January 13, 2006</u>		
To Whom it may concern,		
A Certificate of Correction was filed in the above-referenced patent and 22 months have passed without a response from the Patent Office.		
Following this transmittal is a copy of the return receipt postcard indicating the request was received by the Patent Office as well as a complete copy of the original submission.		
Please do not hesitate to contact me directly at (650) 833-7720 if further information is required.		
Bozicevic Field & Francis LLP		
		
Wilhelm A. Palmen Jr U.S. Docket Manager assisting Bret E. Field		

Ref: TEIK-004

Return Original to: Wilhelm Palmen Jr

Location:

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Express Mail No. **EV687636562US**

Atty. Docket No.: TEIK-004  
USSN: 10/080,526  
Confirmation No.: 8649

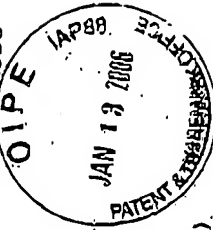
Date Mailed: January 13, 2006  
Filing Date: February 21, 2002  
Atty./Sec.: BEF/djm

Title: "NON-AGGREGATING FLUORESCENT PROTEINS AND METHODS  
FOR USING THE SAME"

Enclosure(s):

- ❖ Transmittal (1 pg)
- ❖ Fee Transmittal (1 pg)
- ❖ USPTO Credit Card Payment Form (1 pg)
- ❖ Petition for Certificate of Correction (2 pgs)
- ❖ Copy of relevant page of issued patent (1 pg)
- ❖ Certificate of Correction (1 pg)

Please Acknowledge receipt of enclosures by PTO date-stamping postcard  
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PTO/SF/21 (05-03)

Approved for use through 04/30/2003, OMB 0851-3031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<h1 style="margin: 0;">TRANSMITTAL FORM</h1> <p style="margin: 5px 0;">(to be used for all correspondence after initial filing)</p>		Application Number	10/080,526
		Filing Date	February 21, 2002
		First Named Inventor	SHUDO, JUTARO
		Group Art Unit	1615
		Examiner Name	GHALI, ISIS A.D.
Total Number of Pages in This Submission <b>7</b>		Attorney Docket Number	TEIK-004
<b>ENCLOSURES (check all that apply)</b>			
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition for Certificate of Correction <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): USPTO Credit Card Payment Form; Certificate of Correction; Copy of relevant page of issued patent; Postcard	
Remarks:			
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>			
Signing Attorney/Agent (Reg. No.)	BRET E. FIELD, 37,620 BOZICEVIC, FIELD & FRANCIS, LLP		
Signature			
Date	January 13, 2006		
<b>EXPRESS MAIL LABEL NO. EV687636562US</b>			

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (12-04)

Approved for use through 07/31/2006, OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b>	
		Application Number	10/080,526
		Filing Date	February 21, 2002
		First Named Inventor	SHUDO, JUTARO
		Examiner Name	GHALI, ISIS A.D.
<input type="checkbox"/> Applicant claims small entity status, See 37 CFR 1.27		Art Unit	1615
TOTAL AMOUNT OF PAYMENT	(\$ 100.00)	Attorney Docket No.	TEIK-004

## METHOD OF PAYMENT (check all that apply)

- ☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_
- ☒ Deposit Account Deposit Account Number: 50-0815 Deposit Account Name: Bozicevic, Field and Francis LLP  
 For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)
- ☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
- ☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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## FEE CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

## 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP =	x					
HP = highest number of total claims paid for, if greater than 20						
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)			
- 3 or HP =	x					
HP = highest number of independent claims paid for, if greater than 3						

## 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x		

## 4. OTHER FEE(S)


Non-English Specification, \$130 fee (no small entity discount)

Other: Certificate of Correction

Fee Paid (\$)

100.00

## SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 37,620	Telephone (650) 327-3400
Name (Print/Type)	Bret E. Field		Date 01/13/2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Express Mail No.

EV 687636562US

<b>PETITION FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.323 FOR APPLICANT MISTAKE</b>  Address to: Certificate of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket Number	TEIK-004
	First Named Inventor	Jutaro Shudo
	Application Number	10/080,526
	Filing Date	February 21, 2002
	Patent Number	6,761,900
	Issue Date	July 13, 2004
	Title	TOPICAL PATCH PREPARATION CONTAINING A DELAYED HYPERSENSITIVITY INDUCER AND METHODS FOR USING THE SAME

Sir:

Applicants petition under 37 C.F.R. § 1.323 for a Certificate of Correction to correct typographical errors in the specification due to Applicant's mistake.

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. Please make the following corrections to the specification:

In column 4, line 15, please replace the word "1-chloro-2,4-nitrobenzene" with -- 1-chloro-2,4-dinitrobenzene --.

The change of "1-chloro-2,4-nitrobenzene" to "1-chloro-2,4-dinitrobenzene" is requested to correct a typographical mistake

The compound name "1-chloro-2,4-dinitrobenzene" is correctly presented in other instances throughout the specification, at for example, Column 1, line 53. Additionally, one of skill in the art would understand that "DNCEB" which is presented throughout the specification, is the acronym for "1-chloro-2,4-dinitrobenzene". Accordingly, the proposed typographical corrections to the specification resulting from Applicants mistake do not constitute new matter and do not require reexamination.

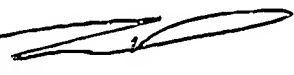
Enclosed is a copy of the relevant page of the issued patent showing the incorrect language of the specification.

USSN: 10/080,526  
Atty Dkt: TEIK-004

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1.13.06

By:   
Bret E. Field  
Registration No. 37,620

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F:\DOCUMENT\TEIK\004\2nd Certificate of Correction Petition TEIK-004.rtf

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,761,900  
DATED : July 13, 2004  
INVENTOR(S) : Jutaro Shudo et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In column 4, line 15, the word "1-chloro-2,4-nitrobenzene" should be replaced with  
-- 1-chloro-2,4-dinitrobenzene --.

MAILING ADDRESS OF SENDER:

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East Palo Alto, CA 94303

PATENT NO: 6,761,900

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US 6,761,900 B2

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skin surface of a subject and maintained at the site of application for a period of time sufficient for an effective amount of the delayed-type hypersensitivity inducer to be administered to the subject, where this maintenance period typically does not exceed about 60 minutes. The subject invention finds use in a variety of applications where the administration of a delayed-type hypersensitivity inducer is desired, and is particularly suited for use in the treatment of HIV associated disease conditions, e.g., AIDS.

### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 provides a cross-sectional view of a topical patch preparation according to the invention.

FIGS. 2 and 3 provide schematic representations of the manufacturing process for topical patch preparations of the invention.

### DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Topical patch preparations that contain a delayed-type hypersensitivity inducer, e.g., 1-dichloro-2,4-dinitrobenzene (DNCEB), and methods for using the same are provided. The subject topical patch preparations are made up of an adhesive gel composition that is present on a support, where the adhesive gel composition includes the delayed-type hypersensitivity inducer, a water-soluble polymer gel, water and a water holding agent. In using the subject topical patch preparations, the topical patch preparations are applied to a skin surface of a subject and maintained at the site of application for a period of time sufficient for an effective amount of the delayed-type hypersensitivity inducer to be administered to the subject, where this maintenance period typically does not exceed about 60 minutes. The subject invention finds use in a variety of applications where the administration of a delayed-type hypersensitivity inducer is desired, and is particularly suited for use in the treatment of HIV associated disease conditions, e.g., AIDS. In further describing the subject invention, the topical patch preparations are described first in greater detail, followed by a review of representative applications in which the subject topical patch preparations find use.

Before the subject invention is described further, it is to be understood that the invention is not limited to the particular embodiments of the invention described below, as variations of the particular embodiments may be made and still fall within the scope of the appended claims. It is also to be understood that the terminology employed is for the purpose of describing particular embodiments, and is not intended to be limiting. Instead, the scope of the present invention will be established by the appended claims.

In this specification and the appended claims, singular references include the plural, unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs.

#### Topical Patch Preparations

As summarized above, the subject invention is directed to topical patch preparations of a delayed-type hypersensitivity inducer agent. The topical patch preparations of the subject invention are characterized by having an effective amount of the delayed type hypersensitivity inducer agent present in a gel adhesive base. FIG. 1 provides a representation of a topical patch preparation described according to the subject invention. As can be seen in FIG. 1, this representative topical patch preparation 10 contains a gel adhesive base 12

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present on a support 14. Each of these components is now described in greater detail.

The gel adhesive base which serves as the delayed-type hypersensitivity inducer retaining layer, is made up of the delayed-type hypersensitivity inducer that is present in, e.g., dissolved in or dispersed in, and adhesive gel base. By "delayed-type hypersensitivity (DTH) inducers" is meant an immunomodulator that elicits immunological response in a subject, such as HIV patients, by increasing the activity of the immune system cells in the body. Delayed-type hypersensitivity inducers are substances that induce Type 4 hypersensitivity when they come into contact with human skin, and they include, but are not limited to: trinitrobenzene sulfonic acid, picryl chloride (PC), 2,4-dinitrofluorobenzene (DNFB), and 1-chloro-2,4-nitrobenzene (DNCEB). In many embodiments, the delayed-type hypersensitivity inducer is DNCEB.

The amount of DTH inducer that is present in the adhesive gel base is an amount sufficient to administer to a subject an effective amount of the agent when applied to a skin surface of the subject, as described in greater detail below. In many embodiments, the amount of DTH inducer present in the adhesive gel base ranges from about 0.01 to 10.0% (w/w), sometimes from about 0.05 to 10.0% (w/w), usually from about 0.1 to 5.0% (w/w) and more usually from about 0.2 to 3.0% (w/w).

The adhesive gel base that includes the DTH inducer, as described above, is made up of a water-soluble high molecular weight substance, water and a water retaining agent. In certain embodiments, the adhesive gel base may further include a cosolvent, e.g., an organic cosolvent. Each of these components is now described separately in greater detail.

Water-soluble high molecular weight substances of interest include water-soluble polymers, where polymers of interest include, but are not limited to: gelatin, starch, agar, mannan, alginate acid, polyacrylic acid, polyacrylate, dextrin, methylcellulose, sodium methylcellulose, hydroxypropylcellulose, sodium carboxymethylcellulose, cellulose gum, carboxyvinyl polymer, polyvinyl alcohol, polyvinylpyrrolidone, Arabia gum, acacia, tragacanth gum, karaya gum, and starch acrylate copolymer or other starch sodium acrylate graft copolymers. Metallic salts of these, as well as the products of cross-linking these by means of organic or inorganic cross-linking agents, are also of interest. These water-soluble polymers can be used to bring out the properties and characteristics of the other starting materials used in the adhesive gel composition, and in practice can be used alone or in combinations of 2 or more. The amount of water soluble high molecular weight substance(s) present in the adhesive gel base generally ranges from about 0.5 to 20, usually from about 2 to 20% (w/w).

While any convenient water may be employed as the water component, of interest are distilled water or ion-exchange water or the like, which is preferred in many embodiments of the subject invention. The amount of water present in the gel adhesive is sufficient to impart the desired physical properties to the gel adhesive, and to improve the swelling of the horny or keratinized layer of the skin to thereby improve the permeability or penetration of the DTH inducing agent(s), where the amount of water in the gel composition generally ranges from about 10 to 80%, usually from about 30 to 60% (w/w).

The water-retaining agent or water-holding agent of the subject adhesive gel compositions is any agent that is capable of at least diminishing the volatilization of water contained in the adhesive gel base so that the water content in the adhesive gel base is maintained at least a substantially